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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,146	11/17/2000	Christopher T. Boyle	6006-018	6734

7590 02/12/2003

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/716,146

Applicant(s)

BOYLE, CHRISTOPHER T.

Examiner

Cheryl L. Miller

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-10 and 12-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-10 and 12-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 18 November 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection.

### ***Information Disclosure Statement***

2. The information disclosure statement filed December 12, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Copies of the references with indicated dash lines were not found.

### ***Drawings***

3. The corrected or substitute drawings were received on November 18, 2002. These drawings are approved.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Referring to claim 24, this is a Markush type claim and requires the format "selected from the group consisting of".

6. Regarding claim 23, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

*Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 2-10 and 12-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown et al. (USPN 6,071,305, cited in previous office action). Brown discloses an endoluminal stent, which includes all limitations recited in the claims.

Referring to claim 5, Brown discloses an endoluminal stent (11, 111) having a 3-D conformation with a central lumen, luminal and abluminal surfaces and a wall thickness between (col.1, lines 15-16; fig.2, 18). Brown discloses a plurality of independent internal cavities (20, figure 9; 114, figure 18) in the thickness of the member, a plurality of openings (22, 28; col.6, line 15; fig.6, 18), communicating between the plurality of cavities and a surface external the stent (col.2, lines 59-65), and at least one bioactive agent (23) disposed in the cavities (20, 114).

Referring to claim 8, Brown discloses a plurality of structural elements (112) defining walls of the stent, and a plurality of discontinuous interior cavities (114; fig.18) traversing the length of the structural elements (112), a plurality of openings communicating between the cavities and external the stent (col.13, lines 30-36; openings as described in previous embodiments, such as 28 in fig.6) and bioactive agent (23) disposed in the cavities.

Referring to claims 15 and 2, Brown discloses an implantable endoluminal stent comprising a 3-D conformation, a plurality of exterior surfaces (luminal and abluminal) and a thickness, wherein the stent is composed of a plurality of interconnected individual structural elements (112), each of the structural elements having at least one internal cavity (114) within the thickness, at least two of a plurality of openings (28) communicating between the cavity (114) and at least two of the exterior surfaces, and at least one bioactive agent (23) disposed in the cavity.

Referring to claims 21 and 22, Brown discloses an implantable medical device (111) comprising a deformable body having a 3-D conformation and thickness, first and second regions (middle and ends of 112), one of the regions adapted to undergo lower strain during deformation (center of the structural elements 112, rather than the connection ends of the struts), at least one internal cavity (114) within the thickness, at least one opening (28) communicating between the cavity (114) and external to the body, the cavity positioned in the lower strain region (fig. 18), and a bioactive agent (23) disposed in the cavity.

Referring to claim 12, this is a product by process claim, wherein vapor deposition is a method of making step. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 R2d. 695, 698, 227 USPQ 964 966 (Fed. Cir. 1985).

Referring to claims 3, 6, 9, 13, and 23; Brown discloses the tubular member or structural body comprises a material selected from the group claimed (col.7, lines 12-19).

Referring to claims 4, 7, 10, 14, and 24, Brown discloses a bioactive or active agent selected from the group claimed (col.5, lines 1-27).

Referring to claims 17, 18, 19, 20, and 25, Brown discloses a degradable plug (matrix 27 or membrane 34; col.8, lines 62-65; col.9, lines 12-21) residing within the at least one of the openings.

9. Claims 2-10 and 12-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Yan (USPN 5,843,172). See figures 6, 11, 12, and respective portions of the specification. Referring to claims 2, 5, 8, 15, 16, 21, and 22, Yan discloses an endoluminal stent (104; fig.1, 9) having a wall thickness and structural members, a plurality of internal cavities (larger pores) and a plurality of openings (smaller pores) connecting the cavities to the stents exterior (col.7, lines 1-16; col.8, lines 45-58), and bioactive agents (therapeutic agent) disposed within the cavities.

Referring to claim 12, this is a product by process claim, wherein vapor deposition is a method of making step. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 R2d. 695, 698, 227 USPQ 964 966 (Fed. Cir. 1985).

Referring to claims 3, 6, 9, 13, and 23, Yan discloses the tubular member or structural body comprising a material selected from the group claimed (col.4, lines 32-39).

Referring to claims 4, 7, 10, 14, and 24, Yan discloses a bioactive or active agent selected from the group claimed (col.5, lines 1-30).

Referring to claims 17, 18, 19, 20, and 25, Yan discloses a degradable plug (coating or matrix 100; fig.11, 12; col.9, lines 15-40) residing within the at least one of the openings.

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*Conclusion*

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl Miller

February 7, 2003

**BRUCE SNOW**  
**PRIMARY EXAMINER**